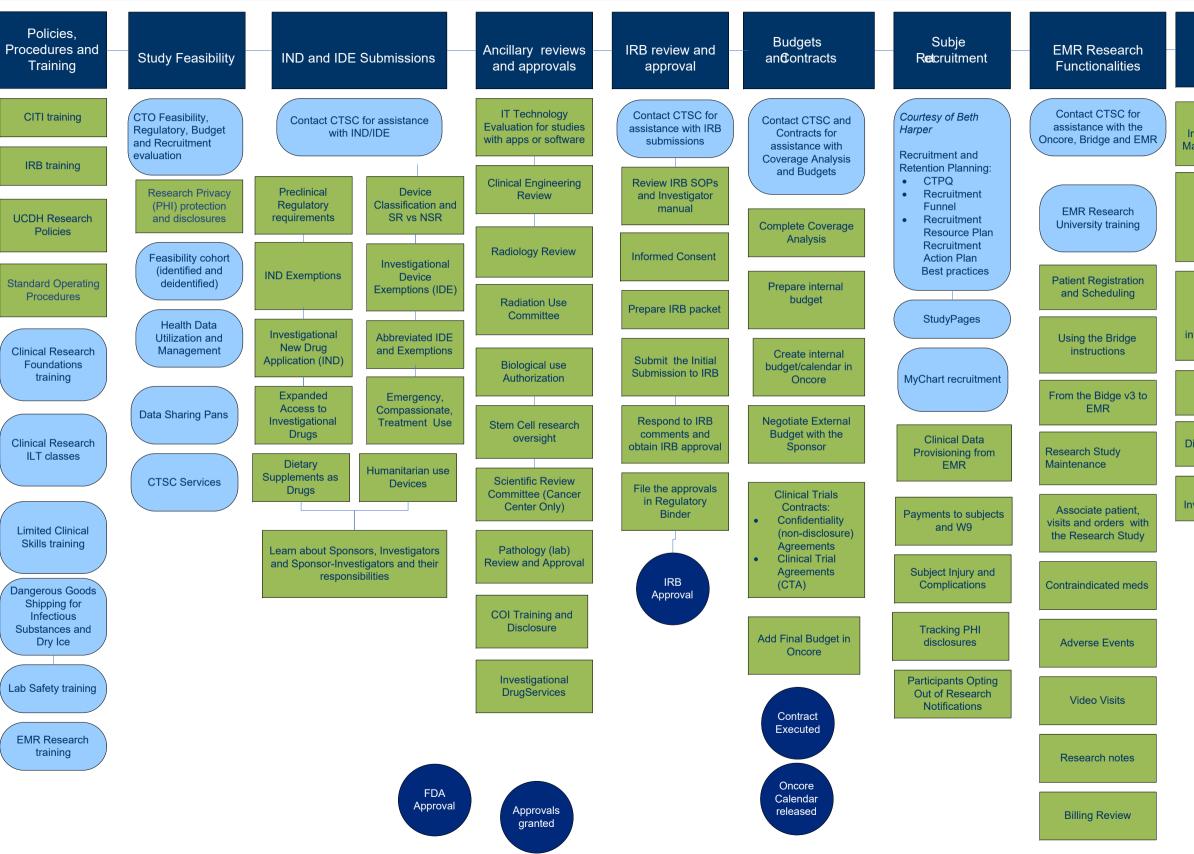


Clinical and Translational Science Center

Clinical Trials at UC Davis Health – At-A-Glance

Updated 2022



Investigational Drug Services	Maintenance and Compliance	Sponsor Invoicing (industry-sponsored trials only)	Study Closure
Overview of Investigational Drug Ianagement process Distribution and maintenance of Investigational product Prescribing, dispensing and transportation of investigational drugs	Contact CTSC for assistance with the regulatory reporting and preparation for audits IRB Reporting: New Information Serious Harms Protocol Deviations Protocol Deviations Protocol Mods Continuing Review Maintain Study Documentation: • Regulatory Binder • Source Document Binder • Case Report Forms Financial Binder IND/IDE Binder	Verify Research account statements, resolves issues w Patient Financial Services Prepare invoice to the Sponsor (traditional) Prepare invoice to the Sponsor (Oncore)	Study Closure activities Publications and PMCID Data Sharing Plans Post information on clinicaltrials.gov
Dietary supplements onitor oversign onitor Drugs Com poun ding Audit s	Monitoring and AuditsDSMB • M • FDA Inspections • Audits by Office of Research Compliance Patient Zero Compliance Reviews		
	EMR: Access to Monitors		Legend Mandatory Highly Advised